

REMARKS

I. INTRODUCTION

Claims 1-33 were previously cancelled. Claims 34 - 60 are pending in the present application. In view of the following remarks, it is respectfully submitted that these claims are in condition for allowance.

II. THE 35 U.S.C. §112 REJECTION SHOULD BE WITHDRAWN

Claim 53 stands rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. (See 2/9/11 Office Action, p. 2). Specifically, the Examiner states that the phrase “at least a portion with a conical shape” seeks to introduce new matter. It was previously presented that the Specification states “[f]urthermore a portion of one or more screw holes may be substantially conical in geometry.” (See Specification, p. 5, ll. 6 - 7). It is further respectfully submitted that the original filing includes claim 19 which recites “characterized in that at least part of at least one of said through holes (3) is conical.” Thus, it is respectfully submitted that claim 53 complies with the written description requirement and the Examiner should withdraw the 35 U.S.C. §112, first paragraph, rejection for this claim.

Claim 50 stands rejected under 35 U.S.C. §112, second paragraph, for being indefinite. (See 2/9/11 Office Action, p. 2). Specifically, the Examiner states that the phrase “wherein at least two of the transverse holes at least partially intersect one another” renders the claim vague and indefinite since it is unclear what structure is being claimed. The Examiner further states that it appears that this recitation is meant to state that the hole axes intersect one another. Initially, independent claim 45 to which claim 50 depends recites “at least three transverse holes extending through the distal end of the nail body” which may be considered a bore hole for purposes of the present argument. As supported in the Specification, Figs. 3-5 provide drawings

for intersecting through holes with a corresponding disclosure in the Specification. Because the transverse holes are bores with a circular area that extends, for example, in a cylindrical path, a partial intersection may occur between two transverse holes. For example, a cross-section of the intersection may include a portion of the circular area of a first transverse hole having a common area with a portion of the circular area of a second transverse hole. Furthermore, it is respectfully submitted that the Examiner is misplaced in assuming claim 50 to mean that the hole axes intersect one another. Because claim 50 depends from claim 45 which recites “at least three transverse holes,” in an embodiment with exactly three transverse holes, two of the transverse holes may intersect while the third transverse hole is disposed such that no common volume is shared. That is, it is possible for a partial intersection in which the axes of the holes never intersect. For example, the hole axes may be skew. Thus, it is respectfully submitted that claim 50 is definite and clear on its face. Therefore, it is respectfully submitted that the Examiner should withdraw the 35 U.S.C. §112, second paragraph, rejection for claim 50.

III. THE 35 U.S.C. §103(a) REJECTIONS SHOULD BE WITHDRAWN

Claims 34 - 48, 50, 51, and 53 - 60 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 6,120,504 to Brumback et al. (hereinafter “Brumback”) in view of U.S. Patent No. 5,472,444 to Huebner et al. (hereinafter “Huebner”). (See 2/9/11 Office Action, p. 3).

Claim 34 recites an intramedullary nail comprising “a nail body having a longitudinal axis, a proximal end configured and dimensioned for coupling to an insertion device, and a distal end having a tip configured and dimensioned for insertion into the intramedullary canal of a long bone” in combination with “at least three transverse holes extending through the distal end of the nail body, each transverse hole defining a hole axis, and all three transverse holes grouped at the distal end within a distance x measured from the tip of the nail body to the axis of the transverse hole furthest from the tip, wherein a projection of the three hole axes of the at least three transverse holes in a plane orthogonal to the longitudinal axis is such that at least two of the

projected hole axes are at an angle α with respect to one another, where $0 < \alpha < 90^\circ$, and *where the distance $x \leq 25d$, where d is either the diameter of the largest of the at least three transverse holes or d is the mean diameter of the at least three holes.*"

The Examiner implies that Brumback does not disclose or suggest the distance of the holes from the tip of the intramedullary nail being less than or equal to twenty five times the diameter of the largest transverse hole or the mean diameter of the transverse holes. The Examiner attempts to cure this deficiency with Huebner by stating that Huebner discloses that the distal tip portion extends about 20-50% the length of the nail beyond the distal most hole to reduce stress concentrations. (See 2/9/11 Office Action, p. 3, citing Huebner, col. 3, ll. 15 - 18; col. 4, ll. 30 - 33). The Examiner further correctly states that neither Brumback nor Huebner relate the distance from the hole axis of the proximal most transverse hole to the distal tip of the nail. However, the Examiner states that the recited distance of claim 34 is obvious since Huebner suggests optimizing the distance for reduction of stress concentrations and the recited function of claim 34 is merely a mathematical expression/manipulation of the prior art teaching of optimizing the distance between the distal end of the nail and the distal-most hole for reducing stress concentrations. (See 2/9/11 Office Action, pp. 5 - 6).

It is respectfully maintained that Brumback or Huebner does not disclose or suggest that "the distance $x \leq 25d$, where d is either the diameter of the largest of the at least three transverse holes or d is the mean diameter of the at least three holes," as recited in claim 34. The Examiner's contention that the recited distance x in claim 34 being obvious is misplaced. As stated in the Specification, "[a] disadvantage of the known nails is the fact that the distal holes are *unnecessarily* far from the distal nail tip which produces a nail-weakening effect." (See Specification, p. 1, ll. 17 - 20). Claim 34 is directed toward at least addressing this particular disadvantage. The Examiner's premise is therefore misplaced as the nail in Huebner is a nail exhibiting the condition where the holes are far from the distal nail tip. That is, the nail in Huebner includes holes and also a distal tip portion that extends beyond the distal-most hole

about 20-50% of the nail length (*i.e.*, “distal holes” being far from the distal tip). Accordingly, it is respectfully submitted that the Examiner’s contention that the function based upon the hole diameter being merely a mathematical expression/manipulation of the prior art teaching is based upon impermissible hindsight in view of the present application.

Furthermore, it is respectfully maintained that the Specification further includes other disadvantages of known nails such as parallel holes being spaced too close to one another, widely spaced parallel or orthogonal holes, and an unnecessarily loose fit to the hole in the nail by the screws traversing the nail. (See Specification, p. 1, l. 22 - p. 2, l. 15). Thus, it is respectfully maintained that both Brumback and Huebner teaching known nails and configured as taught therein fit at least one of the disadvantages that the nail of claim 34 is seeking to address. For example, the nail of Brumback potentially includes an unnecessarily loose fit for a traversing screw such as distal slot 24 and/or proximal slot 25. Because the nails of Brumback and Huebner include at least one of the disadvantages that claim 34 is seeking to address, it is respectfully submitted that the distance x recited in claim 34 is not obvious or capable of being based upon the teachings of either Brumback or Huebner. It is further respectfully submitted that the novel clustering of the transverse holes in the distal end of the nail within the recited range provides the remedy to the above known disadvantages of known nails. Therefore, for least these further reasons, it is respectfully submitted that any assertion that the cited references provides a basis to obviate the recitation of claim 34 is based upon impermissible hindsight.

Thus, it is respectfully submitted that Brumback and Huebner, taken alone or in combination, do not disclose or suggest “all three transverse holes grouped at the distal end within a distance x measured from the tip of the nail body to the axis of the transverse hole furthest from the tip,” “where the distance $x \leq 25d$, where d is either the diameter of the largest of the at least three transverse holes or d is the mean diameter of the at least three holes,” as recited in claim 34. Accordingly, it is respectfully submitted that claim 34 is allowable and the Examiner should withdraw the 35 U.S.C. §103(a) rejection for this claim. Because claims 35 -

44 depend from and, therefore, include the limitations of claim 34, it is respectfully submitted that these claims are also allowable.

Claim 45 includes a recitation substantially similar to claim 34 including “the distance $x < 2(n)(d)$, where n is the number of transverse holes grouped within the distance x from the tip of the nail body and d is either the diameter of the largest of the at least three transverse holes or d is the mean diameter of the at least three holes.” Thus, it is respectfully submitted that claim 45 is allowable for at least the reasons discussed above with reference to claim 34. Because claims 46 - 48, 50 - 51, and 53 - 55 depend from and, therefore, include the limitations of claim 45, it is respectfully submitted that these claims are also allowable.

Claim 56 also includes a recitation substantially similar to claim 34 including “a distance a between the tip and the transverse hole closest to the tip is $a \leq 5d$.” Thus, it is respectfully submitted that claim 56 is allowable for at least the reasons discussed above with reference to claim 34. Because claims 57 - 60 depend from and, therefore, include the limitations of claim 56, it is respectfully submitted that these claims are also allowable.

Claim 49 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback in view of Huebner in further view of U.S. Patent No. 5,041,115 to Frigg et al. (hereinafter “Frigg”). (See 2/9/11 Office Action, p. 4). Claim 52 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback in view of Huebner in further view of U.S. Patent No. 5,766,174 to Perry. (See 2/9/11 Office Action, p. 5). Brumback and Huebner were discussed above. Claim 45 was recited above.

As discussed above, neither Brumback nor Huebner, either alone or in combination, discloses or suggests “the distance $x < 2(n)(d)$, where n is the number of transverse holes grouped within the distance x from the tip of the nail body and d is either the diameter of the largest of the at least three transverse holes or d is the mean diameter of the at least three holes,” as recited in

claim 45. It is respectfully submitted that neither Frigg nor Perry discloses or suggests this recitation of claim 45. Thus, it is respectfully submitted that Brumback, Huebner, Frigg, and Perry, taken alone or in combination, do not disclose or suggest this recitation of claim 45. Because claims 49 and 52 depend from and, therefore, include the limitations of allowable claim 45, it is respectfully submitted that these claims are also allowable.

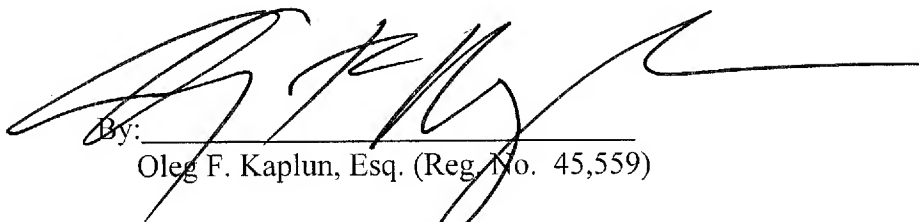
CONCLUSION

In light of the foregoing, Applicant respectfully submits that all of the pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated:

4/7/11


By: _____

Oleg F. Kaplun, Esq. (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276